PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

H. Darrel DARBY

Appln. No.: 10/019,669

Confirmation No.: 6168

Filed: May 13, 2002

For: HEALING SHOE OR SANDAL

Docket No: A7705

Group Art Unit: 3728

Examiner: Marie D. PATTERSON

SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. A check for the small entity statutory fee of $250.00 is attached. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: August 3, 2005

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

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I. REAL PARTY IN INTEREST

Based on information supplied by Appellant and to the best knowledge of the Appellant's legal representative, the real party in interest is the assignee, DARCO INTERNATIONAL, INC., by virtue of an Assignment recorded on May 13, 2002 at Reel 013097, Frame 0620.

II. RELATED APPEALS AND INTERFERENCES

There are no other related appeals or interferences known to Appellant, Appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

Claims 1-42 are all of the pending claims. Dependent method claims 33 and 34 remain withdrawn from consideration. Claims 3, 6, 9, 12-30, and 35-40 are allowed.

Claims 1, 2, 4, 5, 7, 8, 10, 11, 31, 32, 41 and 42 stand rejected. All rejected claims are appealed. The rejected claims are set forth in the attached Appendix.

IV. STATUS OF AMENDMENTS

Subsequent to the Final Rejection of March 7, 2005, Appellant submitted an Amendment Under 37 C.F.R. § 1.116, which was filed on May 5, 2005, in which independent claims 1 and 31 were amended to incorporate the recitations of dependent claims 41 and 42, respectively. Further, the Amendment Under 37 C.F.R. § 1.116 of May 5, 2005 cancelled claims 41 and 42. In the Advisory Action of May 18, 2005, the Examiner indicated that this Amendment would not be entered because the proposed amendments allegedly raised new issues and were not deemed to place the application in better form for appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention aims to provide a shoe or sandal which aids in the offloading, or reducing weight or pressure, from a specific area of the foot, which may be used in the treatment of infections, ulcerations, and other conditions of the foot. *See* Specification at paragraph 1, page 1. Such conditions may result from diabetes, rheumatoid arthritis, vascular conditions, neuropathy, trauma to the foot, or other conditions where it is desirable to redistribute weight away from an infected or traumatized area of the foot to be treated. *See* Specification at paragraph 20, pages 4-5.

More specifically, the invention is directed to shoe or sandal which includes a molded out sole, an upper portion, and an adjustable insole. *See* Specification at paragraph 20, pages 4-5. Further, the shoe is designed to accommodate the use of a plurality of layers of various insole materials which provides for offloading specific areas of the foot to promote healing of fractures, ulcers, or infections when healing may otherwise be delayed by weight bearing pressure. *See* Specification at paragraph 21, page 5.

The outsole of the shoe or sandal has a substantially rectangular opening in a top surface thereof which is adapted for accommodating a metatarsal shank which reduces motion in the shoe and in the corresponding portion of the foot, as well as providing additional strength to the out sole. *See* Specification at paragraph 25, page 6.

Further, the shoe or sandal includes a circumferential counter which extends around the circumference of the top portion of the out sole and forms an opening, cavity, depression, or pocket that allows the upper portion of the shoe to be conjoined with or counter sunk into the out sole. *See* Specification at paragraph 23, page 5. The circumferential counter therefore permits extra depth in the upper portion of the shoe or sandal in which a variety of insole layers can be placed, while also providing a low profile. *Id.* Thus, a plurality of insole layers may be disposed in the out sole cavity and surrounded by the upper assembly and the out sole circumferential counter. *See* Specification at paragraph 23, pages 5-6.

The cavity formed by the circumferential counter presents a lower profile in that the insole layers are confined within the molded out sole below the level of the upper portion of the shoe rather than in the shoe upper itself. *See* Specification at paragraph 29, page 8. The out sole and the circumferential counter may be molded in one piece and are designed to add stability to the foot while providing space for the insole, including the plurality of insole layers, within the out sole cavity to prevent shifting of the insole layers and permit offloading of specific areas of the foot. *See* Specification at paragraph 28, pages 7-8. Accordingly, the cavity provides greater stability for the foot and prevents the plurality of insole layers from shifting, which would otherwise occur in conventional shoes if a plurality of insole layers were inserted above an out sole level. *See* Specification at paragraph 24, page 6.

The plurality of insole layers which are provided may include a plurality of differing insole layer thickness, materials, hardnesses and densities. *See* Specification at paragraph 29, page 8. Further, each of the plurality of insole layers is separably removable. *See* Specification

at paragraph 33-34, pages 10-11. The plurality of insole layers are stacked on top of one another in the cavity of the shoe or sandal, and are each separably removable and capable of being rearranged so as to be stacked in different orders. *Id.*

The order of plurality of insole layers can be arranged according to a particular patient's condition. *See* Specification at paragraph 33, page 10. For example, the order of at least three insole layers can be rearranged as healing of a foot ulceration progresses. *Id.* In addition, the insole layers may be skived in an area near an ulceration which is on the plantar surface of the foot. *Id.*

The upper of the shoe is constructed of an outer covering with an inner liner which is separable from the outer covering. *See* Specification at paragraph 27, page 7. Further, a specific portion of the outer covering may be removed in an area over a lesion while leaving the inner lining in place for protection. *Id.*

The bottom surface of the base portion of the outsole may be provided with a rocker bottom which is adapted to permit easy ambulation while also providing a stable platform for standing. *See* Specification at paragraph 30, pages 8-9. The rocker bottom in combination with the metatarsal shank allows a patient to ambulate comfortably while reducing motion of the foot, thereby reducing the friction caused by foot movement within the shoe. *Id.* A fitting marker may further be provided on the outsole to assist in proper fitting of the shoe. *See* Specification at paragraph 35, pages 11.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 2, 4, 5, 7, 8, 10, 11, 31, 41 and 42 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Darby (U.S. Patent No. 5,491,909, hereinafter "Darby '909") in view of Darby et al. (U.S. Patent No. 5,370,133, hereinafter "Darby '133"), and further in view of Grim et al. (U.S. Patent No. 5,329,705, hereinafter "Grim").

Claim 32 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Darby '909 in view of Darby '133 and Grim, and further in view of Kellerman et al. (U.S. Patent No. 5,799,414).

VII. ARGUMENT

Appellant's arguments are initially focused on independent claims 1 and 31 and, thereafter, on the dependent claims.

1. Claims 1, 2, 4, 5, 7, 8, 10, 11, 31, 41 and 42 In View of Darby '909, Darby '133 and Grim

a. Independent claim 1

For the reasons set forth below, the Examiner has failed to establish *prima facie* obviousness because the combination of Darby '909, Darby '133 and Grim fails to teach or suggest all the limitations of claim 1, the disclosure of Grim teaches away from the claimed invention, and the Examiner has not provided a sufficient motivation to combine the references.

The combination of Darby '909, Darby '133 and Grim fails to teach or suggest all the claim limitations.

Claim 1 defines a medical shoe comprising, *inter alia*, an "out sole having a circumferential counter portion extending upward circumferentially from the top of the base portion of the out sole around the base portion of the outsole thereby providing a cavity in the out sole". Further, claim 1 recites an insole assembly "having a plurality of insole layers disposed in the out sole cavity and surrounded by the upper assembly and the out sole circumferential

counter". In addition, claim 1 recites each of the plurality of insole layers is "separably removable", "said plurality of insole layers are stacked on top of one another, and said plurality of insole layers are capable of being rearranged so as to be stacked in different orders". Claim 1 also requires that "the out sole circumferential counter prevents each of the plurality of insole layers from shifting within the out sole cavity when the insole layers are stacked in each of the different orders".

The combined teachings of Darby '909, Darby '133 and Grim do not teach or suggest all the limitations of claim 1.[1] For instance, Darby '909 discloses a medical shoe having a sole assembly and an upper assembly. The sole assembly includes an outer sole. The inner sole 18 is bonded to the upper surface of the outer sole by an adhesive. *See* Darby '909 at col. 2, lines 27-30. The Examiner concedes that Darby '909 fails to teach "a circumferential counter portion and the exact layered insole." *See* Office Action of May 8, 2005 at page 2.

To compensate for the deficiencies in the disclosure of Darby '909, the Examiner initially turns to Darby '133, which the Examiner contends teaches the claimed circumferential counter portion. Darby '133 discloses a molded polyurethane boot which is closed at both the rear and side and which includes an open front. *See* Darby '133 at col. 4, line 65 - col. 5, line 6. Specifically, the Examiner refers only to element 16A in Figure 1 of Darby '133.[2] As taught by Darby '133, lip 18A is a "semi-circular vertical wall portion" which is provided in "the open toe

[1] Appellant addresses the improper motivation to combine these references below.

[2] Appellant notes that element 16A of Figure 1 is apparently referred to as "lip 18A" in the description of Figure 1, as element 16A does not appear to be mentioned in the detailed description of Darby '133.

area 80" and rises above the upper surface of insole 24. *See* Darby '133 at col. 5, lines 1-8. However, as clearly shown in Figure and described by Darby '133, the wall portion of lip 18A is only provided at the open toe area. Thus, the combination of Darby '909 and Darby '133 would at most teach a semi-circular vertical wall provided at the open toe area.

In the grounds of rejection, the Examiner next turns to the teachings of Grim. As stated by the Examiner, "Grim teaches providing an insole with a plurality of different layers (52, 64, and 56) which are separately removable and are 'capable of being rearranged in a different order' (due to the layers being completely detachable from one another) and one having a removable area (68) for use in a medical shoe." *See* Office Action of May 8, 2005 at pages 2-3.

Thus, the Examiner identifies inner sole assembly 52, lower air bladder 64, and an area 56 of the soft goods type support member 20 of Grim as the claimed plurality of different layers. As taught by Grim, a footgear is provided with an inner sole assembly 52 "which is preferably mounted within the soft goods support member 20 by a layer of hook type securing material 54". *See* Grim at col. 4, lines 9-15.

Further, Grim teaches that "[i]nner sole assembly 52 includes a lower air bladder 64 which may contain a layer of foam material, and an upper resilient layer 66 constituting separate removable sections which together form a normally substantially smooth surface of engagement by the foot. *See* Grim at col. 4, lines 22-26 (emphasis added). Thus, two of the alleged "layers" identified by the Examiner are not individual layers at all. Indeed, as described by Grim and shown in Figure 2, lower air bladder 64 is included in inner sole assembly 52 and therefore cannot properly be considered to be "separably removable".

Further, Grim teaches that the individual resilient sections, such as section 68, of upper resilient layer 66 have hook or loop type securing material on their lower surface, which mate with corresponding hook and loop material on the upper surface of the air bladder 64. *See* Grim at col. 4, lines 36-42. Therefore, even if upper resilient layer 66 is considered as one of the "plurality of insole layers", the lip 18A of Darby '133 would clearly not prevent the individual resilient sections of upper resilient layer 66 from shifting because the sections would not be secured to the air bladder 64 if rearranged in a different order, and the multiple individual sections being no longer attached to a securing layer of air bladder 64 would necessarily shift within the out sole cavity. *See* Amendment of January 21, 2005 at page 22.

In the *non-limiting* embodiment shown in Fig. 3 of the Specification, a circumferential counter 120 prevents shifting of the layers 600, 620, 640, and 660. As shown in Figs. 8-13, these layers 600, 620, 640, and 660 can be rearranged in different orders. The circumferential counter 120 prevents shifting of the layers 600, 620, 640, and 660 even when they are arranged in an order different than that shown in Fig. 3.

Moreover, inner sole assembly 52 and area 56 of soft goods type support member 20, likewise cannot properly be considered to correspond to the claimed "plurality of insole layers." Indeed, Appellant previously noted,

> Even assuming *arguendo* that a circumferential counter would prevent the layers 20 and 52 of Grimm from shifting when the inner sole assembly 52 is stacked on top of the soft goods support member 20, as shown in Fig. 3, there is no teaching or suggestion that the circumferential counter would prevent the layers 20 and 52 of Grimm from shifting within the out sole cavity if the soft goods support member 20 is stacked on top of the inner

> sole assembly 52. This is because the soft goods support member 20 and inner sole assembly 52 are designed so that when the inner sole assembly 52 is provided on top of the soft goods support member 20, the side flaps 48 of the soft goods support member 20 hold the inner sole assembly 52 in place within the frame 14. However, if the order of the soft goods support member 20 and inner sole assembly 52 were reversed and the inner sole assembly were placed on the bottom of the soft good support member 20, then the inner sole assembly 52 would not be held in place by the side flaps 48 of the soft goods support member 20 within frame 14. Instead, the inner sole assembly 52 would be loosely placed within the frame 14 and would not be prevented from shifting.

See Amendment of January 21, 2005 at pages 22-23.

Further, as noted previously, Grim teaches that the inner sole assembly 52 is "mounted within the soft goods support member 20 by a layer of hook type securing material 54" which engages the inner surface of the soft goods type support member. *See* Grim at col. 4, lines 9-15. The Examiner, though, has not addressed the deficiencies of Grim's teaching, but mischaracterizes Appellant's arguments as an attack on Grim individually. To wit, the Examiner stated,

> In response to applicant's arguments directed towards the newly added phrases in claims 1 and 31, it has been held that one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references. In re Keller, 208 USPQ 871 (CCPA 1981). The modifying reference Darby (5370133) clearly shows and teaches a circumferential counter 16a which is also part of element 34 which clearly is shown as extending up around the heel of the foot and therefore it clearly would result in preventing shifting of all the layers of the footwear which are located below the foot of the wearer and above the sole layer.

See Office Action of March 7, 2005 at page 4.

Initially, Appellant clearly indicated that "there is no combination of Darby '909, Darby '133 and Grimm that would reasonably teach or suggest the claimed medical shoe..." (Amendment at page 22) (emphasis added). Thus, in characterizing Appellant's remarks as an attack on Grim individually, the Examiner ignores the fact that Darby '909 and Darby '133 do not teach an insole with a plurality of different layers. ("Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it."). MPEP § 707.07(f). Indeed, the Examiner relies on Grim to allegedly teach an insole with the claimed plurality of insole layers.

Moreover, as noted above, the combined teachings of Darby '909 and Darby '133 at most have provided a medical shoe with an lip portion 18A surrounding only an open toe area. Thus, the combined teaching of Darby' 909, Darby '133 and Grim clearly does not teach all the claim limitations at least because the alleged insole layers of Grim would not be prevented from shifting by the lip of Darby '133 within the out sole cavity if stacked in different orders.

The insole structure of Grim teaches away from the claimed invention.

As noted above, Grim teaches that the inner sole assembly 52, lower air bladder 64, and an area 56 of the soft goods type support member 20 are provided in one specific order. Indeed, the inner sole assembly 52 is attached on top of the soft goods support member 20. Further evidence of that these elements are intended to be arranged in a specific order is demonstrated by the hook type securing material which secures the inner sole assembly to the surface of the soft goods support member 20, which lies beneath. *See* Grim at col. 4, lines 9-15. Moreover, the

inner sole assembly 52 includes the lower air bladder 64. Thus, these elements cannot reasonably be considered separate layers.

In addition, the separate removable section 68 of the upper resilient layer 66, even if they were all removed and somehow rearranged as a separate layer, would undoubtedly not be prevented from shifting, as the individual sections would no longer be secured by the securing material to the upper surface of the bladder and would thus shift within a out sole cavity. The Manual Of Patent Examining Procedure ("MPEP") mandates that "the references must be considered as a whole," and therefore requires the Examiner to consider and confront those passages in the applied art that lead away from the claimed invention. MPEP §§ 2141, 2141.02

Accordingly, Grim, which not only teaches that inner sole elements are arranged in a specific order, but are also secured in the specific order by providing securing material designed only to be applied in one specific order, necessarily would teach away from the claimed invention, in which the plurality of insole layers are capable of being rearranged so as to be stacked in different orders and the outsole circumferential counter prevents each of the plurality of insole layers from shifting within the outsole cavity when the insole layers are stacked in each of the different orders.

The Examiner has failed to provide a sufficient motivation to combine Darby '909, Darby '133 and Grim.

To establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a particular reference or to combine reference teachings. *See* Manual Of Patent Examining Procedure ("MPEP") at Section 2143.

The USPTO is held to a *rigorous* standard when trying to show that an invention would have been obvious in view of the combination of two or more references or modification of a single reference. *See, In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002), *citing, e.g., In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.").

The case law emphasizes that the "need for specificity pervades this authority." *In re Lee* at 1433 (emphasis added) (*citing In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed").

However, the Examiner's grounds of rejection do not meet the Federal Circuit's *rigorous* standard for demonstrating that the claimed subject matter would have been obvious in view of the applied art. For instance, as motivation to combine Darby '133 and Grim with Darby '909,

the Examiner merely provides the following conclusory opinion: "It would have been obvious to provide the outsole with a counter portion as taught by Darby '133 and to provide an insole having a plurality of different separable layers as taught by Grim in the shoe of Darby '909 to provide greater stability to the outsole/upper construction and to increase the cushioning and medial benefits of the insole construction taught by Grim." (Office Action at page 3).

Initially, Appellant notes that the Examiner fails to identify any portion of either Darby '133 or Grim in support of the alleged motivation to combine their teachings with Darby '909. Further, it is entirely unclear from the grounds of rejection whether the Examiner contends that providing greater stability to the outsole upper construction and increasing the cushioning and "medial benefits" on the insole construction are separate motivations which respectively apply to Darby '133 and Grim individually, or whether the Examiner contends that the motivation applies equally to both references.

Notwithstanding this ambiguity, the Examiner has not pointed to any portion of the actual disclosure of Darby '133 and Grim in support of the alleged motivation to combine their teachings with Darby' '909. Indeed, the Examiner offers only conclusory opinions regarding alleged benefits increased stability and increased cushioning and medial benefits of the insole to the medical shoe of Darby '909. However, there is no showing that a lip portion of Darby '133 provided at an open toe area of the shoe would provide the asserted benefit, nor is there any showing that one of skill would have been motivated to rearrange the alleged layers of Grim in clear contradiction to their intended arrangement.

Thus, the alleged motivation provided by the Examiner strongly suggests that the Examiner has relied upon *improper hindsight construction*, using Appellant's disclosure, *not the objective teachings of the prior art*, as a template for picking and choosing various features from multiple references to address the limitations of the claims.[3] Indeed, the motivation asserted by the Examiner clearly is not consistent with a "rigourous application of the requirement for a showing of the teaching or motivation to combine" and the Examiner has therefore failed to establish *prima facie* obviousness.

In view of the foregoing, the rejection of claim 1 is improper because the Examiner has not established *prima facie* obviousness. Accordingly, Appellant requests that the rejection of claim 1 be reversed. Further, Appellant submits that claims 2, 4, 5, 7, 8, 10 and 11 are allowable at least by virtue of depending from claim 1, and likewise requests the reversal of the rejection of these claims.

b. Independent claim 31

Independent claim 31 defines an assembly of a healing shoe having an upper assembly, an out sole assembly with a cavity therein, and an out sole circumferential counter, comprising, *inter alia*, a plurality of separably removable insole layers disposed in the out sole cavity, the separably removable insole layers surrounded by the upper assembly and the out sole circumferential counter integrally attached to the out sole assembly and the upper assembly. In

[3] As noted above, Appellant disagrees with the Examiner's conclusion that the combination of Darby '909, Darby '133 and Grim teaches all the claim limitations.

addition, "the plurality of insole layers are stacked on top of one another, and said insole layers are capable of being rearranged so as to be stacked in different orders". Claim 31 also requires that "the out sole circumferential counter prevents each of the plurality of insole layers from shifting within the out sole cavity when the insole layers are stacked in each of the different orders".

Thus, Appellant submits that the above arguments with respect to claim 1 are equally applicable to claim 31. Therefore, the rejection of claim 31 should be reversed for similar reasons.

c. Dependent claims 41 and 42

Claims 41 and 42, which respectively depend from independent claims 1 and 31, require that "said plurality of separably removable layers include at least three layers."

However, the combination of Darby '909, Darby '133, and Grim cannot properly be relied upon to teach at least *three separably removable* layers, wherein the out sole circumferential counter prevents each of the plurality of layers from shifting within the out sole cavity when the layers are stacked in each of different orders.

As noted above, the Examiner identifies the inner sole assembly 52, lower air bladder 64, and resilient inner sole 66[4] as corresponding to the recited three separably removable insole layers. However, the layers of Grimm's inner sole assembly 52 are not *separably removable* so

[4] *See* Office Action dated March 7, 2005 at page 2, and Grimm at Figs. 2 & 3.

that the out sole circumferential counter prevents each of the plurality of layers from shifting within the out sole cavity when the layers are stacked in each of the different orders.

That is, the individual removable areas 68 of Grim's upper resilient area 66 (See Grimm at Fig. 2) cannot correspond by themselves to one of the recited plurality of separably removable insole layers. If the removable areas 68 were removed from the inner sole assembly 52, the circumferential counter would not prevent the removable areas from shifting within the out sole cavity when the insole layers are stacked in each of the different orders. In fact, even if all of the removable areas 68 were removed together from the inner sole assembly 52 in an attempt to provide a separably removable layer, a circumferential counter would not prevent the removable areas 68 from shifting within the out sole cavity *if the removable areas 68 were the bottom of three layers*. Indeed, separated removable areas 68, which would necessarily not be secured to the upper surface of air bladder 64, as intended, would clearly shift within the shoe even if lip 18A of Darby '133 were present. Thus, at least for this reason, claims 41 and 42 should be allowed in addition to being allowable by virtue of depending from claims 1 and 31.

2. Claim 32 In View of Darby '109, Darby '133, Grim and Kellerman et al.

Without conceding that Kellerman et al. teaches the limitations of claim 32 or that the asserted motivation to combine is proper, Appellant submits that claim 32 is patentable at least by virtue of depending from claim 31. Therefore, reversal of the rejection of claim 32 is requested.

VIII. CONCLUSION

Pursuant to the foregoing arguments, Appellants note that claims 1, 2, 4, 5, 7, 8, 10, 11, 31, 32, 41 and 42 are patentable. Accordingly, Appellants respectfully request that the Examiner's rejection be reversed and the present application be allowed at the earliest possible opportunity.

Unless a check is submitted herewith for the fee required under 37 C.F.R. §41.37(a) and 1.17(c), please charge said fee to Deposit Account No. 19-4880.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE
23373
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Date: August 3, 2005

CLAIMS APPENDIX

CLAIMS 1, 2, 4, 5, 7, 8, 10, 11, 31, 32, 41 AND 42 ON APPEAL:

1. A medical shoe for use in supporting a patient's foot comprising:

an out sole;

an upper assembly secured to and partially surrounded by the out sole;

an insole assembly substantially enclosed by the out sole and the upper assembly;

the out sole having a base portion generally corresponding with the plantar aspect of a human foot and of varying thickness and having a substantially rectangular opening in a top surface thereof adapted for accommodating a metatarsal shank;

the out sole having a circumferential counter portion extending upward circumferentially from the top surface of the base portion of the out sole around the base portion of the out sole thereby providing a cavity in the out sole;

the upper assembly including a heel portion, an intermediate portion and a toe portion, the heel section and intermediate section integrally connected;

the upper assembly adapted to surround at least the heel, sides and dorsal portions of the human foot;

the upper assembly attached to the top surface of the base portion of the out sole and the circumferential counter of the out sole, and extending in a dorsal direction from the top surface of the base portion of the out sole along the circumferential counter;

the insole assembly having a plurality of insole layers disposed in the out sole cavity and surrounded by the upper assembly and the out sole circumferential counter;

the plurality of insole layers provided to include at least one of a plurality of differing insole layer thickness, materials, hardnesses and densities;

wherein each of the plurality of insole layers is separably removable,

wherein said plurality of insole layers are stacked on top of one another, and said plurality of insole layers are capable of being rearranged so as to be stacked in different orders; and

wherein the out sole circumferential counter prevents each of the plurality of insole layers from shifting within the out sole cavity when the insole layers are stacked in each of the different orders.

2. The medical shoe as claimed in claim 1, wherein the insole assembly includes at least a first and a second insole layer wherein the first and second layers are an Ethyl Vinyl Acetate (EVA) material, and the second layer has a durometer less than the first layer.

4. The medical shoe as claimed in claim 1, wherein the opening for the metatarsal shank is centered laterally and extends distally from a location substantially corresponding to the distal 1/3 of the metatarsals in a plantar aspect of a corresponding foot to be supported by the medical shoe, and

wherein the metatarsal shank accommodated therein is comprised of one of a metallic material and a rigid plastic material.

5. The medical shoe as claimed in claim 2, wherein the opening for the metatarsal shank is centered laterally and extends distally from a location substantially corresponding to the distal 1/3 of the metatarsals in a plantar aspect of a corresponding foot to be supported by the medical shoe; and

wherein the metatarsal shank accommodated therein is comprised of one of a metallic material and a rigid plastic material.

7. The medical shoe as claimed in claim 4, wherein a bottom surface of the base portion of the out sole has a unique rocker shape, a rocker bottom, adapted to permit easy ambulation while also providing a stable platform for standing;

the rocker bottom having a flat mid-section in upwardly and rearwardly oblique relation to a tapered heel section and upwardly and forwardly oblique relation to a tapered toe section.

8. The medical shoe as claimed in claim 5, wherein a bottom surface of the base portion of the out sole has a unique rocker shape, a rocker bottom, adapted to permit easy ambulation while also providing a stable platform for standing;

the rocker bottom having a flat mid-section in upwardly and rearwardly oblique relation to a tapered heel section and upwardly and forwardly oblique relation to a tapered toe section.

10. The medical shoe as claimed in claim 7, wherein the apex of the rocker bottom which is adapted to form the oblique angle between the mid-section and the tapered toe section is located just below a fitting marker just proximal to the metatarsal heads, the oblique angle between the tapered heel section and the mid-section is located just below mid-heel, and the taper of the heel section is adapted so as to cause the heel to strike at the oblique angle between the tapered heel section and the mid-section.

11. The medical shoe as claimed in claim 8, wherein the apex of the rocker bottom which is adapted to form the oblique angle between the mid-section and the tapered toe section is located just below a fitting marker just proximal to the metatarsal heads, the oblique angle between the tapered heel section and the mid-section is located just below mid-heel, and the taper of the heel section is adapted so as to cause the heel to strike at the oblique angle between the tapered heel section and the mid-section.

31. An assembly of a healing shoe having an upper assembly, an out sole assembly with a cavity therein, and an out sole circumferential counter, comprising:

a plurality of separably removable insole layers disposed in the out sole cavity;

the separably removable insole layers surrounded by the upper assembly and the out sole circumferential counter integrally attached to the out sole assembly and the upper assembly, the

insole assembly including an oval opening within at least one of the insole layers adapted to be directly under an area of a human foot;

the plurality of separably removable insole layers provided to include at least one of a plurality of differing insole layer thickness, materials, hardnesses and densities,

wherein said insole layers are stacked on top of one another, and said insole layers are capable of being rearranged so as to be stacked in different orders; and

wherein the out sole circumferential counter prevents each of the plurality of insole layers from shifting within the out sole cavity when the insole layers are stacked in each of the different orders.

32. The assembly of claim 31, wherein edges of the oval opening are skived such that the opening farther away from the area to be treated is slightly larger than the opening nearer the area to be treated.

41. The medical shoe as claimed in claim 1, wherein said plurality of separably removable insole layers include at least three layers.

42. The assembly of a healing shoe as claimed in claim 31, wherein said plurality of separably removable insole layers include at least three layers.